

10-24-05

PTO/SB/21 (09-04)


OIP E IAP72  
OCT 20 2005  
PATENT AND TRADEMARK OFFICE

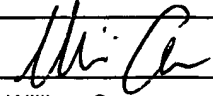
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OCT 20 2005  
PATENT AND TRADEMARK OFFICE

TRANSMITTAL FORM

to be used only for correspondence after initial filing

Application Number	09/730,329
Filing Date	December 4, 2000
First Named Inventor	John
Art Unit	1653
Examiner Name	Kam, C.
Attorney Docket Number	015270-006460US
Total Number of Pages in This Submission	17

ENCLOSURES (Check all that apply)		
<input checked="" type="checkbox"/> Fee Transmittal Form	<input type="checkbox"/> Drawing(s)	<input type="checkbox"/> After Allowance Communication to TC
<input type="checkbox"/> Fee Attached	<input type="checkbox"/> Licensing-related Papers	<input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences
<input type="checkbox"/> Amendment/Reply	<input type="checkbox"/> Petition	<input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief)
<input type="checkbox"/> After Final	<input type="checkbox"/> Petition to Convert to a Provisional Application	<input type="checkbox"/> Proprietary Information
<input type="checkbox"/> Affidavits/declaration(s)	<input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address	<input type="checkbox"/> Status Letter
<input type="checkbox"/> Extension of Time Request	<input type="checkbox"/> Terminal Disclaimer	<input checked="" type="checkbox"/> Other Enclosure(s) (please identify below):
<input type="checkbox"/> Express Abandonment Request	<input type="checkbox"/> Request for Refund	1. Return postcard
<input checked="" type="checkbox"/> Supplemental Information Disclosure Statement (3 pgs.) PTO/SB/08A (5 pgs.) PTO/SB/08B (6 pgs.)	<input type="checkbox"/> CD, Number of CD(s) _____	2. One Hundred Two (102) references*
<input type="checkbox"/> Certified Copy of Priority Document(s)	<input type="checkbox"/> Landscape Table on CD	
<input type="checkbox"/> Reply to Missing Parts/ Incomplete Application	Remarks	The Commissioner is authorized to charge any additional fees to Deposit Account 20-1430.
<input type="checkbox"/> Reply to Missing Parts under 37 CFR 1.52 or 1.53	* Not included in "Total Number of Pages In This Submission"	
<b>SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT</b>		
Firm Name	Townsend and Townsend and Crew LLP	
Signature		
Printed name	Mark G. Sandbaken, Ph.D.	
Date	October 20, 2005	Reg. No. 39,354

CERTIFICATE OF TRANSMISSION/MAILING			
Express Mail Label: EV 529 865 418 US and EV 529 865 404 US			
I hereby certify that this correspondence is being deposited with the United States Postal Service with "Express Mail Post Office to Address" service under 37 CFR 1.10 on this date October 20, 2005 and is addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below.			
Signature			
Typed or printed name	William Carr	Date	October 20, 2005

Effective 02/08/2004.  
Fees pursuant to the Patent and Trademark Fee Schedule, 37 CFR 1.101, and the Appropriations Act, 2005 (H.R. 4818).

# FEE TRANSMITTAL

☐ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT (\$ ) 180.00

## Complete if Known

Application Number 09/730,329  
Filing Date December 4, 2000  
First Named Inventor John  
Examiner Name Kam, C.  
Art Unit 1653  
Attorney Docket No. 015270-006460US

### METHOD OF PAYMENT (check all that apply)

☐ Check ☐ Credit Card ☐ Money Order ☐ None ☐ Other (please identify): \_\_\_\_\_  
☒ Deposit Account Deposit Account Number: 20-1430 Deposit Account Name: Townsend and Townsend and Crew LLP

For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)

☒ Charge fee(s) indicated below ☐ Charge fee(s) indicated below, except for the filing fee  
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### FEE CALCULATION

#### 1. BASIC FILING, SEARCH, AND EXAMINATION FEES

Application Type	FILING FEES		SEARCH FEES		EXAMINATION FEES		Fees Paid (\$)
	Small Entity	Fee (\$)	Small Entity	Fee (\$)	Small Entity	Fee (\$)	
Utility	300	150	500	250	200	100	
Design	200	100	100	50	130	65	
Plant	200	100	300	150	160	80	
Reissue	300	150	500	250	600	300	
Provisional	200	100	0	0	0	0	

#### 2. EXCESS CLAIM FEES

Fee Description	Small Entity	
	Fee (\$)	Fee (\$)
Each claim over 20 or, for Reissues, each claim over 20 and more than in the original patent	50	25
Each independent claim over 3 or, for Reissues, each independent claim more than in the original patent	200	100
Multiple dependent claims	360	180

Total Claims Extra Claims Fee (\$) Fee Paid (\$) Multiple Dependent Claims  
-20 or HP = \_\_\_\_\_ x \_\_\_\_\_ = \$0 Fee (\$) Fee Paid (\$)

HP = highest number of total claims paid for, if greater than 20

Indep. Claims Extra Claims Fee (\$) Fee Paid (\$)  
-3 or HP = \_\_\_\_\_ x \_\_\_\_\_ = \$0

HP = highest number of independent claims paid for, if greater than 3

#### 3. APPLICATION SIZE FEE

If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

Total Sheets Extra Sheets Number of each additional 50 or fraction thereof Fee (\$) Fee Paid (\$)  
- 100 = \_\_\_\_\_ / 50 = \_\_\_\_\_ (round up to a whole number) x \_\_\_\_\_ = \_\_\_\_\_

#### 4. OTHER FEE(S)

Non-English Specification, \$130 fee (no small entity discount)

Other: Information Disclosure Statement (after office action)

Fees Paid (\$)

180.00

#### SUBMITTED BY

Signature	<i>Mark G. Sandbaken</i>	Registration No. (Attorney/Agent) 39,354	Telephone (650) 326-2400
Name (Print/Type)	Mark G. Sandbaken, Ph.D.		Date October 20, 2005

"Express Mail" Label No. EV 529865418 US, EV 529865404 US  
Date of Deposit October 20, 2005

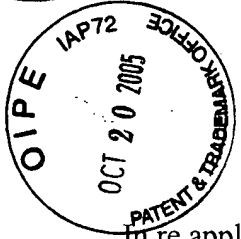
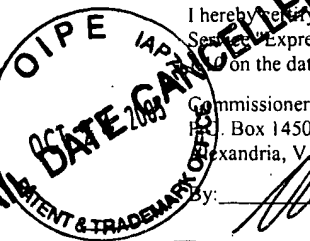
PATENT  
Attorney Docket No.: 015270-006460US  
Client Reference No.: 228-US-NEW4

I hereby certify that this is being deposited with the United States Postal Service Express Mail Post Office to Addressee" service under 37 CFR on the date indicated above and is addressed to:

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

By: 

William Carr



**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of:

Varghese John et al.

Application No.: 09/730,329

Filed: December 4, 2000

For: BETA-SECRETASE ENZYME  
COMPOSITIONS AND METHODS

Examiner: C. Kam

Art Unit: 1653

INFORMATION DISCLOSURE  
STATEMENT UNDER 37 CFR §1.97 and  
§1.98

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

The references cited on the attached PTO/SB/08A and PTO/SB/08B forms are being called to the attention of the Examiner. Copies of the references [in compliance with the requirements of 1287 OG 163] are enclosed. It is respectfully requested that the cited references be expressly considered during the prosecution of this application, and the references be made of record therein and appear among the "references cited" on any patent to issue therefrom.

Applicant also cites commonly owned copending applications directed to related subject matter:

08/480,498 filed 06/07/1995 issued as 5,744,346 on 04/28/1998

08/659,984 filed 06/07/1996 issued as 5,942,400 on 08/24/1999

08/660,531 filed 06/07/1996 issued as 6,221,645 on 04/24/2001

10/26/2005 HLE333 00000041 201430 09730329

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09/054,334 filed 04/02/1999 issued as 6,329,163 on 12/11/2001  
09/404,578 filed 09/23/1999 issued as 6,852,482 on 02/08/2005  
09/471,669 filed 12/24/1999  
09/723,722 filed 11/28/2000  
09/724,566 filed 11/28/2000 issued as 6,627,739 on 09/30/2003  
09/724,571 filed 11/28/2000 issue fee paid on 05/19/2005  
09/724,568 filed 11/28/2000  
09/724,569 filed 11/28/2000  
10/778,675 filed 02/12/2004  
11/069,377 filed 02/28/2005  
11/089,918 filed 03/25/2005  
11/090,399 filed 03/25/2005  
11/090,872 filed 03/25/2005

Applicant further cites the following commonly owned abandoned applications directed to related subject matter:

08/485,152 filed 06/07/1995  
60/114,408 filed 12/31/1998  
60/119,571 filed 02/10/1999  
60/139,172 filed 06/15/1999  
09/501,708 filed 02/10/2000  
09/723,739 filed 11/28/2000  
10/099,922 filed 03/15/2002

Applicants understand the Examiner can access papers from the prosecution of the cited cases electronically via PALM. However, if the Examiner has difficulty obtaining papers from that source he or she is invited to call the undersigned who will be happy to supply them.

As provided for by 37 CFR 1.97(g) and (h), no representation is being made that a search has been conducted or that this statement encompasses all the possible relevant information, and no inference should be made that the information and references cited are, or are considered to be material to patentability because they are in this statement. No inference should be made that the information and references cited are prior art merely because they are in this statement.

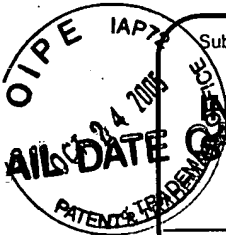
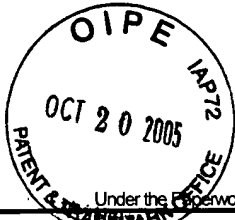
This IDS is being filed before the mailing date of the final Office Action or Notice of Allowance. Please charge the IDS fee of \$180 to Deposit Account No. 20-1430. Please deduct any additional fees from, or credit any overpayment to, the above-noted Deposit Account.

Respectfully submitted,



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Reg. No. 39,354

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MGS:crf



PTO/SB/08A (10-01)  
Approved for use through 10/31/2002. OMB 0651-0031  
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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Substitute for form 1449A/PTO

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 1 of 11

### Complete if Known

Application Number	09/730,329
Filing Date	12/04/2000
First Named Inventor	John
Art Unit	1653
Examiner Name	Kam, C.
Attorney Docket Number	015270-006460US

### U.S. PATENT DOCUMENTS

Examiner	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number Kind Code <sup>2</sup> (if known)			
	153	6,852,482	02-08-2005	Gurney et al.	
	149	6,844,148	01-18-2005	Gurney et al.	
	148	6,835,565	12-28-2004	Gurney et al.	
	91 B2	6,828,117	12-07-2004	Gurney et al.	
	139	6,825,023	11-30-2004	Gurney et al.	
	113	6,797,487	09-28-2004	Gurney et al.	
	114	6,790,610	09-14-2004	Gurney et al.	
	115	6,753,163	06-22-2004	Gurney et al.	
	116	6,737,510	05-18-2004	Gurney et al.	
	117	6,727,074	04-27-2004	Gurney et al.	
	118	6,706,485	03-16-2004	Gurney et al.	
	119	6,699,671	03-02-2004	Gurney et al.	
	154	6,627,739	09-30-2003	Anderson	
	120	6,500,667	12-31-2002	Gurney et al.	
	121	6,440,698	08-27-2002	Gurney et al.	
	122	6,420,534	07-16-2002	Gurney et al.	
	1	6,361,975	03-26-2002	Christie et al.	
	2	6,358,725	03-19-2002	Christie et al.	
	138	6,329,163	12-11-2001	Anderson et al.	
	3	6,319,489	11-20-2001	Powell et al.	
	4	6,319,689	11-20-2001	Powell et al.	
	5	6,313,268	11-06-2001	Hook	
	6	6,245,884	06-12-2001	Hook	
	7	6,245,964	06-12-2001	McConlogue et al.	
	8	6,221,645	04-24-2001	Chrysler et al.	

Examiner Signature		Date Considered	
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<sup>1</sup> EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>2</sup> Applicant's unique citation designation number (optional). <sup>3</sup> Kind Codes of U.S. Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>4</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>5</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>6</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>7</sup> Applicant is to place a check mark here if English language Translation is attached.

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## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 2 of 11

### Complete if Known

Application Number	09/730,329
Filing Date	12/04/2000
First Named Inventor	John
Art Unit	1653
Examiner Name	Kam, C.
Attorney Docket Number	015270-006460US

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Examiner	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number Kind Code <sup>2</sup> (if known)			
	9	6,211,428	04-03-2001	Singh et al.	
	10	6,162,630	12-19-2000	Powell et al.	
	11	6,025,180	02-15-2000	Powell et al.	
	13	5,877,015	03-02-1999	Hardy et al.	
	141	5,863,756	01-26-1999	Barr et al.	
	14	5,849,560	12-15-1998	Abraham	
	15	5,837,672	11-17-1998	Schenk et al.	
	16	5,795,963	08-18-1998	Mullan	
	17	5,766,846	06-16-1998	Schlossmacher et al.	
	18	5,750,349	05-12-1998	Suzuki et al.	
	19	5,744,346	04-28-1998	Chrysler et al.	
	20	5,733,768	03-31-1998	Dixon et al.	
	21	5,593,846	01-14-1997	Schenk et al.	
	22	5,455,169	10-03-1995	Mullan	
	23	5,424,205	06-13-1995	Dovey et al.	
	140	2004/0234976	11-25-2004	Gurney et al.	
	123	2004/0166507	08-26-2004	Gurney et al.	
	124	2004/0048303	03-11-2004	Gurney et al.	
	125	2004/0043408	03-04-2004	Gurney et al.	
	128	2002/0081634	06-27-2002	Gurney et al.	
	130	2002/0037315	03-28-2002	Gurney et al.	
	131	2001/0021391	09-13-2001	Gurney et al.	
	142	10/817,979		Gurney et al.	
	143	10/477,076		Gurney et al.	
	144	09/668,314		Gurney et al.	
	94	09/548,370		Gurney et al.	
	97	09/548,369		Gurney et al.	

Examiner  
Signature

Date  
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<sup>1</sup> EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Kind Codes of U.S. Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

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# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 3 of 11

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	95	09/548,365		Gurney et al	
	27	09/404,133		Gurney et al.	
	28	09/277,229		Citron et al.	
	29	60/210,292		Hong et al.	
	30	60/178,368		Lin et al.	
	31	60/177,836		Lin et al.	
	152	60/169,232		Gurney et al.	
	32	60/168,060		Lin et al.	
	33	60/155,493		Gurney et al.	
	34	60/141,363		Lin et al.	
	35	60/139,172		Anderson et al.	
	36	60/119,571		Basi et al.	
	37	60/114,408		Basi et al.	
	38	60/101,594		Gurney et al.	

## FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Country Code <sup>3</sup>	Foreign Patent Document Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
	170	EP	1 445 263	A1	08-11-2004			
	171	EP	855 442	A2	07-29-1998			
	39	EP	855 444	A2	07-29-1998			
	40	EP	848 062	A2	06-17-1998			
	166	GB	2 364 059	B	01-14-2004			
	167	GB	2 389 114	B	02-04-2004			
	168	GB	2 389 113	B	02-04-2004			
	169	GB	2 389 182	B	02-04-2004			
	134	WO	01/50829	A2	07-19-2001			

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Date  
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# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 4 of 11

## Complete if Known

Application Number	09/730,329
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Art Unit	1653
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	135	WO	01/49098	A2	07-12-2001			
	136	WO	01/49097	A2	07-12-2001			
	48	WO	01/38487	A2	05-31-2001			
	49	WO	01/36600	A1	05-25-2001			
	50	WO	01/31054	A1	05-03-2001			
	51	WO	01/29563	A1	04-26-2001			
	137	WO	01/23533	A2	04-05-2001			
	52	WO	01/00665	A2	01-04-2001			
	53	WO	01/00663	A2	01-04-2001			
	47	WO	00/69262	A1	11-23-2000			
	46	WO	00/68266	A1	11-16-2000			
	45	WO	00/58479	A1	10-05-2000			
	44	WO	00/56871	A2	09-28-2000			
	43	WO	00/47618	A3	08-17-2000			
	42	WO	00/23576	A2	04-27-2000			
	41	WO	00/17369	A2	03-30-2000			
	54	WO	99/64587	A1	12-16-1999			
	55	WO	99/46281	A2	09-16-1999			
	57	WO	99/34004	A2	08-07-1999			
	59	WO	99/31236	A2	06-24-1999			
	145	WO	98/37226	A1	08-27-1998			
	60	WO	98/26059		06-18-1998			
	188	WO	98/22597	A2	05-28-1998			
	61	WO	98/21589		05-22-1998			
	62	WO	98/13488		04-02-1998			
	63	WO	98/11236		03-19-1998			
	103	WO	97/47314		12-18-1997			

Examiner  
Signature

Date  
Considered

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Sheet 5 of 11

**Complete if Known**

Application Number	09/730,329
Filing Date	12/04/2000
First Named Inventor	John
Art Unit	1653
Examiner Name	Kam, C.
Attorney Docket Number	015270-006460US

**FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Country Code <sup>3</sup>	Foreign Patent Document Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
	56	WO	96/40885	A2	12-19-1996			
	58	WO	96/31122	A1	10-10-1996			
	102	WO	96/20725	A2	07-11-1996			

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				Filing Date	12/04/2000
				First Named Inventor	John
				Art Unit	1653
				Examiner Name	Kam, C.
Sheet	6	of	11	Attorney Docket Number	015270-006460US

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	104	BALDWIN et al., "Crystal structures of native and inhibited forms of human cathepsin D: Implications for lysosomal targeting and drug design," <u>PNAS</u> , 90:6796-6800 (1993).	
	181	BORK, P., "Powers and Pitfalls in Sequence Analysis: The 70% Hurdle," <u>Genome Research</u> , 10:398-400 (2000).	
	179	BROUN et al., "Catalytic Plasticity of Fatty Acid Modification Enzymes Underlying Chemical Diversity," <u>Science</u> , 282:131-133 (1998).	
	105	BROWN et al., "Evaluation of Cathepsins D and G and EC 3.4.24.15 as Candidate $\beta$ -Secretase Proteases Using Peptide and Amyloid Precursor Protein Substrates," <u>Journal of Neurochemistry</u> , 66:2436-2445 (1996).	
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Sheet 7 of 11

**Complete if Known**

Application Number	09/730,329
Filing Date	12/04/2000
First Named Inventor	John
Art Unit	1653
Examiner Name	Kam, C.
Attorney Docket Number	015270-006460US

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	156	Examination Report for United Kingdom Application 00121314.9 dated July 21, 2003.	
	157	Examination Report for United Kingdom Application 00121314.9 dated October 30, 2003.	
	158	Examination Report for United Kingdom Application 0318112.0 dated November 19, 2003.	
	159	Search and Examination Report for United Kingdom Application 0318112.0 dated September 24, 2003.	
	160	Search and Examination Report for United Kingdom Application 0318107.0 dated September 25, 2003.	
	161	Search and Examination Report for United Kingdom Application 0318113.8 dated September 25, 2003.	
	162	Examination Report for United Kingdom Application 0318113.8 dated November 19, 2003.	
	163	Examination Report for European Application 00919298.0 dated October 30, 2003.	
	164	Search Report for European Application 04006991.6 dated June 11, 2004.	
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Sheet 8 of 11

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	67	HAASS et al., "Amyloid $\beta$ -peptide is Produced by Cultured Cells During Normal Metabolism," <u>Nature</u> , 359:322-325 (1992).	
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			Filing Date	12/04/2000	
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	173	KRISTIE, T. M., "The Mouse Homologue of the Human Transcription Factor C1 (Host Cell Factor)," <u>J. Biol. Chem.</u> , 272(42):26749-26755 (1997).	
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	81	SINHA et al., "Purification and Cloning of Amyloid Precursor Protein $\beta$ -Secretase from Human Brain," <u>Nature</u> , 402:537-540 (1999).		
	172	SUN et al., "Gene Structure, Chromosomal Localization, and Expression of the Murine Homologue of Human Proteinase Inhibitor 6 (PI-6) Suggests Divergence of PI-6 from the Ovalbumin Serpins*," <u>J. Biol. Chem.</u> , 270(27): 16089-16096 (1995).		
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	83	TANZI et al., "Protease Inhibitor Domain Encoded by an Amyloid Protein Precursor mRNA Associated with Alzheimer's Disease," <u>Nature</u> , 331:528-530 (1988).		
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